

**SPECIFICATION**

(Case No. 98,420)

TO ALL WHOM IT MAY CONCERN:

Be it known that we, MARK T. RISE, a citizen of the United States and resident of Monticello, Minnesota, and MICHAEL D. BAUDINO, a citizen of the United States and resident of Coon Rapids, Minnesota, have invented certain new and useful improvements in

**TECHNIQUES FOR SELECTIVE ACTIVATION OF NEURONS IN THE  
BRAIN, SPINAL CORD PARENCHYMA OR PERIPHERAL NERVE**

of which the following is a specification.

Assignee: Medtronic, Inc.  
7000 Central Avenue, N.E.  
Minneapolis, Minnesota 55432

## **BACKGROUND OF THE INVENTION**

This patent application is a continuation of U.S. Patent Application Serial No. 09/302,519, filed April 30, 1999, for which priority is claimed. This parent application is incorporated herein by reference in its entirety.

5

### **Field of the Invention**

The present Invention relates to techniques for providing treatment therapy to neural tissue, and more particularly relates to techniques for selectively delivering treatment therapy to neural tissue located within a volume of the brain, spinal cord, or peripheral nerve.

### **Description of Related Art**

10

Electrical stimulation techniques have become increasingly popular for treatment of pain and various neurological disorders. Typically, an electrical lead having one or more electrodes is implanted near a specific site in the brain or spinal cord of a patient. The lead is coupled to a signal generator which delivers electrical energy delivered through the electrodes creates an electrical field causing excitation of the nearby neurons directly or indirectly treat the pain or neurological disorder.

15

20

Presently, only highly skilled and experienced practitioners are able to position a stimulation lead in such a way that the desired volume of brain tissue is influenced and desired results are obtained over time with minimal side effects. It requires much time and effort to focus the stimulation on the population of nerve cells subserving the appropriate function in the desired body region during surgery. These leads cannot be moved by the physician without requiring a second surgery.

25

A major practical problem with these systems is that the response of the nervous system may change in time. For example, when treating pain even if paresthesia covers the area in pain perfectly during surgery, the required paresthesia pattern often changes later due to lead migration,

histological changes (such as the growth of connective tissue around the stimulation electrode), neural plasticity or disease progression. As a result, the electrical energy is directed to stimulate undesired portions of the brain or spinal cord. Redirecting paresthesia without requiring a second surgery is therefore highly desirable. With present single channel, linear electrode array approaches, however, it is difficult to redirect stimulation effects afterwards, even though limited readjustments can be made by selecting a different contact combination, pulse rate, pulse width or voltage. These problems are found not only with spinal cord stimulation (SCS), but also with peripheral nerve stimulation (PNS), depth brain stimulation (DBS), cortical stimulation and also muscle or cardiac stimulation.

In the case of DBS where an electrical lead is implanted within the brain, it is particularly critical that the lead be properly positioned. If the lead is not properly positioned and needs to be moved, it must be removed and re-inserted thereby increasing the risk of bleeding and damage to the neuropile. It is therefore desirable to place the lead within the brain in one attempt and avoid subsequent movement or repositioning of the lead.

Recent advances in this technology have allowed the treating physician or the patient to steer the electrical energy delivered by the electrode once it has been implanted within the patient. For example, U.S. Patent No. 5,713,922 entitled "Techniques for Adjusting the Locus of Excitation of Neural Tissue in the Spinal Cord or Brain," issued on February 3, 1998 to and assigned to Medtronic, Inc. discloses one such example of a system for steering electrical energy. Other techniques are disclosed in Application Serial Nos. 08/814,432 (filed March 10, 1997) and 09/024,162 (filed February 17, 1998). Changing the electric field distribution changes the distribution of neurons

recruited during a stimulus output thus provides the treating physician or the patient the opportunity to alter the physiological response to the stimulation. The steerability of the electric field allows the user to selectively activate different groups of nerve cells without physically moving the electrode.

These steering techniques, however, are limited to primarily two-dimensional steering since the electrodes are positioned in a linear or planar configuration. In the case of deep brain stimulation (DBS), the stimulation treatment requires stimulation of a volume of neural tissue. Since the exact location of the desired tissue is unknown, it is desirable to steer the electrical field in more than just two-dimensional space.

Another problem with DBS is that the insertion of electrical leads within the brain presents risks of bleeding or damage to the brain tissue. Where multiple leads are inserted within the brain, this risk also multiplies. Often during placement of a lead within the brain, the lead is not placed in the desired location. The lead must be removed and re-inserted into the brain. Each re-insertion of the lead poses additional risk of injury.

Accordingly, there remains a need in the art to provide a two- or three-dimensional steerable electrical stimulation device that may be implanted within the brain or spinal cord parenchyma that requires minimal adjustment of the lead position.

## SUMMARY OF THE INVENTION

As explained in more detail below, the present invention overcomes the above-noted and other shortcomings of prior techniques for electrical stimulation of the brain, spinal cord parenchyma and peripheral nerve. The present invention provides a technique for insertion of electrode leads that require minimal adjustment once the lead has been inserted. Additionally, the present invention enables the user to selectively stimulate neurons or neural tissue within a specific volume of tissue. In a preferred embodiment, the present invention includes a cannula, a plurality of leads, and at least one therapy delivery element or electrode at the distal ends of each of the leads. The cannula has a lumen and at least two openings at its distal end. The leads may be inserted into the cannula's lumen and projected outward at the distal end from each of the openings along a predetermined trajectory. A therapy delivery device, such as a signal generator, is coupled to one or more therapy delivery elements, such as electrodes. The signal generator is capable of selectively providing electrical energy via the electrode to create an electrical field. The system may selectively adjust the electrical field created by the electrical energy. Optionally, a sensor may be included for generating a signal related to the extent of a physical condition for treating a neurological disorder or pain. The sensor signal may then be used to adjust at least one parameter of the electrical energy provided to the electrode.

In another embodiment, the present invention is implemented within a drug delivery system. In such a case, the therapy delivery device may be a pump and the therapy delivery element is a catheter. Alternatively, both electrical stimulation and drug delivery may be implemented.

By using the foregoing techniques, electrical stimulation and/or drug delivery may be adjusted and/or steered to a precise target within a volume of neural tissue to provide the desired treatment therapy. Further, the present invention provides a method of lead placement that allows the surgeon to explore a larger volume of brain tissue using only a single pass of the lead introducer into the brain which will reduce the inherent risk of surgery. Examples of the more important features of this invention have been broadly outlined above so that the detailed description that follows may be better understood and so that contributions which this invention provides to the art may be better appreciated. There are, of course, additional features of the invention which will be described herein and which will be included within the subject matter of the claims appended hereto.

## **BRIEF DESCRIPTION OF THE DRAWINGS**

These and other advantages and features of the invention will become apparent upon reading the following detailed description and referring to the accompanying drawings in which like numbers refer to like parts throughout and in which:

5           Figure 1 is a schematic view of a patient having an implant of a neurological stimulation system employing a preferred form of the present invention to stimulate the subthalamic nucleus of the patient;

Figure 2 is a cross sectional view of brain B showing implantation of a cannula within the brain;

10           Figure 3 is a sagittal view of a subthalamic nucleus showing implantation of electrical leads having electrodes at the distal ends;

Figures 4-7 are exemplary illustrations of various electrical lead configurations capable of selectively stimulating a volume of neural tissue in accordance with the present invention;

15           Figure 8 is an illustration of a cannula in accordance with a preferred embodiment of the present invention;

Figures 9 and 9A are cross sectional views of a cannula in accordance with another embodiment of the invention;

Figure 10 is an illustration of a guiding mechanism to be inserted within a cannula for directing the trajectory of the electrical leads of the present invention;

20           Figure 11 is an illustration of another embodiment of the present invention wherein one or more drugs are delivered;

Figures 12A-B illustrate another embodiment of the present invention wherein the outer leads are pre-formed so that the distal ends will curl out from the inner lead when unconstrained by an introducing cannula;

Figure 13 is a schematic block diagram of a microprocessor and related circuitry used in the preferred embodiment of the invention;

Figures 14-18 are flow charts illustrating a preferred form of a microprocessor program for generating stimulation pulses to be administered to the brain;

Figure 19 is a schematic block diagram of a sensor and analog to digital converter circuit used in the preferred embodiment of the invention;

Figure 20 is a flow chart illustrating a preferred form of a microprocessor program for utilizing the sensor to control the treatment therapy of the brain;

Figure 21 is a cross-sectional view of the present invention implanted subdurally within the cerebral spinal fluid;

Figure 22 is a cross-sectional view of the present invention implanted subdurally within spinal cord parenchyma; and

Figure 23 is a cross-sectional view of the present invention implanted within a peripheral nerve.



## **DESCRIPTION OF THE PREFERRED EMBODIMENTS**

Figure 1 is a schematic view of a patient 10 having an implant of a neurological stimulation system employing a preferred form of the present invention to stimulate the subthalamic nucleus of the patient. The preferred system employs an implantable therapy delivery device or a pulse generator 14 to produce a number of independent stimulation pulses which are sent to a region of the brain parenchyma such as the subthalamic nucleus by insulated leads coupled to therapy delivery devices or electrodes 16A-18A (Figure 3). Each lead is inserted within cannula 22A. Alternatively, two or more electrodes 16A-18A may be attached to separate conductors included within a single lead. Figure 2 is a cross section of brain B showing implantation of cannula 22A within the brain. The specific locations within the brain are discussed in further detail herein.

Device 14 is implanted in a human body 120 in the location shown in Figure 1. Body 120 includes arms 122 and 123. Alternatively, device 14 may be implanted in the abdomen or any other part of the body.

Implantable pulse generator 14 is preferably a modified implantable pulse generator available from Medtronic, Inc. under the trademark ITREL II with provisions for multiple pulses occurring either simultaneously or with one pulse shifted in time with respect to the other, and having independently varying amplitudes and pulse widths. This preferred system employs a programmer 20 which is coupled via a conductor 31 to a telemetry antenna 24. The system permits attending medical personnel to select the various pulse output options after implant using telemetry communications. While the preferred system employs fully implanted elements, systems employing partially implanted generators and radio-frequency coupling may also be used in the practice of the

present invention (e.g., similar to products sold by Medtronic, Inc. under the trademarks X-trel and Matrix).

Figure 3 is a sagittal view of the subthalamic nucleus 10 of brain B at approximately 11mm lateral to the midline. The distal ends of insulated leads 16-18 within cannula 22A terminate in electrodes 16A-18A. The electrodes may be conventional DBS™ electrodes, such as model 3387 sold by Medtronic, Inc. Alternatively, electrodes 16A-18A may be constructed like electrical contacts 56, 58 and 60 shown in PCT International Publication No. WO 95/19804, entitled "Multichannel Apparatus for Epidural Spinal Cord Stimulation" (Holsheimer et al., filed 24 January 1994, published 27 July 1995) which is incorporated by reference in its entirety. Electrodes 16A-18A are positioned in a two- or three-dimensional predetermined geometric configuration as described in further detail herein such that they are distributed throughout various portions of a volume of brain parenchyma such as the subthalamic nucleus. An anode/cathode relationship is established between electrodes 16A-18A in the manner described in PCT Publication No. WO 95/19804. For example, electrodes 16A and 18A may be established as anodes (+) and electrode 17A may be established as a cathode (-). The physician or patient may configure the system to utilize any combination of electrodes 16A-18A to selectively establish a locus of action potentials.

Pulses may then be applied to specific electrodes as taught in the PCT Publication No. WO 95/19804 to direct a locus of action potentials in the brain. Pulses in electrodes 16A-18A create a locus of excitation of nerve cells. As preferred, the electrical pulses are independently adjustable within each electrode such that the locus of excitation may be adjusted to deliver the desired therapy.

For example, the pulses may overlap in time and may be independently variable in amplitude to best control the areas of activation, or they may also have independently variable pulse widths.

In accordance with the present invention, a volume of neural tissue may be stimulated by placement of electrical leads in a non-linear configuration. Figures 4-7 illustrate various electrical lead configurations capable of selectively stimulating a volume of neural tissue. Lead 400 of Figure 4 includes six electrodes at its distal end defining the sides of a cube 405 as shown in Figure 4A. Cube 405 roughly represents the volume of brain parenchyma that electrodes may potentially stimulate. The subset of tissue actually stimulated is determined by the selection of the particular electrodes to pulse and the pulsing parameters. Lead 400 is preferably five separate leads bundled together. The center lead 401 may be advanced beyond the distal ends of the four outer leads 402 forming the outer surface of cube 405. In this embodiment, the inner lead may also be extended a variable distance from the distal tip of the outer tube. As an example, lead 400 of Figure 5 shows the situation when five (5) electrodes at its distal end are positioned in a planar configuration as shown in Figure 5A. This is accomplished by advancing inner lead 401 only as far as needed to position the most distal electrode in the same plane as those curled leads. As illustrated in Figures 6, 6A, 7 and 7A those skilled in the art will appreciate that any number of lead and electrode configurations may be possible and still be considered within the spirit and scope of the present invention. For example, another electrode may be on inner lead 401 and positioned right at the point where leads split apart. The lead of the present invention may also provide for drug delivery as shown in Figure 11 and discussed herein.

Each electrode may be individually connected to signal generator 14 through a conductor in cables 22 which is coupled to signal generator 14 in the manner shown in Figure 1. Alternatively, each electrode may be coupled to signal generator 14 in a manner disclosed in Application Serial No. 09/024,162 entitled "Living Tissue Stimulation and Recording Techniques with Local Control of Active Sites" and filed February 17, 1998. The electrodes of Figures 4-7 may be selectively powered as an anode, cathode or neither. The operator or patient preferably may also selectively adjust the energy, amplitude or pulse parameters delivered to each electrode. The selective control over each electrode may be achieved by signal generator 14 via programmer 20 or a separate controller such as that disclosed in Application Serial Nos. 09/024,162. Advantageously, the present invention allows the locus of excitation to be selectively adjusted and/or steered to precisely target portions of the brain to achieve the desired treatment therapy. The steering may be accomplished in the manner described in U.S. Patent No. 5,713,922 which is incorporated herein by reference in its entirety.

Figure 8 is an illustration of an alternative embodiment of a three dimensional electrode array having a lumen 800 for directing the trajectory of the electrical leads of the present invention. Lumen 800 is permanently introduced into the brain parenchyma to a region roughly in the center of the volume of brain the user wishes to influence. Lumen 800 has a proximal end 805 for accepting one or more leads 815A-818A and a distal end 810 having openings 815-818 for directing leads 815A-818A in accordance with a desired trajectory. Ends of leads 815A-818A may protrude from openings 815-818 as needed to achieve the desired geometric configuration. It is preferred that leads 815A-818A protrude out from openings 815-818 along a predetermined trajectory.

Advantageously, the present invention avoids any slicing movement of leads 815A-818A while moving outwardly from the central axis of lumen 800 thereby minimizing any risks of damage or bleeding to the brain tissue. Optionally, leads 815A-818A may be made of a silicon material having a predetermined bend or memory along its body to ensure that leads 815A-818A project from an opening at the desired angle.

Openings 815-818 preferably direct leads 815A-818A along a predetermined angle and trajectory. Figure 9 shows a cross-sectional view of cannula 905 along its distal end showing the two openings. Figure 9A illustrates a lead 920 as it is positioned within cannula 905 and lead end 910 is guided out from cannula 905 by opening 915. Figure 10 illustrates the interior portion 905 of a cannula capable of receiving four leads. Interior portion may be inserted within a standard cannula. Those skilled in the art will appreciate that any number of configurations are possible to achieve the desired geometric configurations of the electrodes. Additionally, lead members may contain more than one electrode near their distal end further expanding the geometric options for selectively activating subsections of brain volume.

The present invention is implanted by first implanting cannula 800 so that its distal end 810 is at a predetermined location within the brain. Each lead is then individually inserted within cannula 800 and positioned such that the electrode is at the desired location within the brain.

Figure 12 illustrates another embodiment of the present invention wherein four outer leads 450 are pre-formed so that the distal ends will curl out from the inner lead 465 when unconstrained by an introducing cannula 460. Outer leads 450 and inner lead 465 may be a single lead structure. Cannula 460 may be a standard cannula of a sufficiently large lumen to accept a plurality of leads.

Cannula 460 may also be utilized to implant the leads of Figures 4-7. Referring back to Figure 12, lead 450 may be given a predetermined curvature or memory so that the four outer leads 450 curl out when no longer constrained by the inner wall of cannula 460 as shown in Figure 12A. Again, the outer leads 450 preferably extend out into the brain parenchyma along a predetermined trajectory to minimize injury to brain tissue.

Optionally, the present invention may incorporate a closed-loop feedback system to provide automatic adjustment of the electrical stimulation therapy. The system may incorporate a sensor 130 to provide feedback to provide enhanced results. Sensor 130 can be used with a closed loop feedback system in order to automatically determine the level of electrical stimulation necessary to provide the desired treatment. Sensor 130 may be implanted into a portion of a patient's body suitable for detecting symptoms of the disorder being treated. Sensor 130 is adapted to sense an attribute of the symptom to be controlled or an important related symptom. Sensors suitable for this purpose may include, for example, those disclosed in U.S. Patent No. 5,711,316 entitled "Method Of Treating Movement Disorders By Brain Infusion" assigned to Medtronic, Inc., which is incorporated herein by reference in its entirety. In cases where the attribute of the symptom is the electrical activity of the brain, stimulating electrodes may be intermittently used to record electrical activity.

As shown in Figure 19, the output of sensor 130 is coupled by a cable 132 comprising conductors 134 and 135 to the input of analog to digital converter 206. Alternatively the output of the sensor 130 could communicate through a "body bus" communication system as described in U.S. Patent No. 5,113,859 (Funke), assigned to Medtronic which is incorporated by reference in its

entirety. Alternatively, the output of an external feedback sensor 130 would communicate with the implanted pulse generator 14 or pump 10A through a telemetry down-link. The output of the analog to digital converter 206 is connected to terminals EF2 BAR and EF3 BAR. Such a configuration may be one similar to that shown in U.S. Patent No. 4,692,147 ("147 Patent") except that before converter 206 is connected to the terminals, the demodulator of the '147 patent (identified by 101) would be disconnected.

Alternatively, one or more electrodes implanted within the brain may serve as a sensor or a recording electrode. When necessary these sensing or recording electrodes may delivery stimulation therapy to the treatment site.

For some types of sensors, a microprocessor and analog to digital converter will not be necessary. The output from sensor 130 can be filtered by an appropriate electronic filter in order to provide a control signal for signal generator 14. An example of such a filter is found in U.S. Patent No. 5,259,387 "Muscle Artifact Filter, Issued to Victor de Pinto on November 9, 1993, incorporated herein by reference in its entirety.

Closed-loop electrical stimulation can be achieved by a modified form of the ITREL II signal generator which is described in Figure 13. The output of the analog to digital converter 206 is connected to a microprocessor 200 through a peripheral bus 202 including address, data and control lines. Microprocessor 200 processes the sensor data in different ways depending on the type of transducer in use. When the signal on sensor 130 exceeds a level programmed by the clinician and stored in a memory 204, increasing amounts of stimulation will be applied through an output driver 224.

The stimulus pulse frequency is controlled by programming a value to a programmable frequency generator 208 using bus 202. The programmable frequency generator provides an interrupt signal to microprocessor 200 through an interrupt line 210 when each stimulus pulse is to be generated. The frequency generator may be implemented by model CDP1878 sold by Harris Corporation. The amplitude for each stimulus pulse is programmed to a digital to analog converter 218 using bus 202. The analog output is conveyed through a conductor 220 to an output driver circuit 224 to control stimulus amplitude. Microprocessor 200 also programs a pulse width control module 214 using bus 202. The pulse width control provides an enabling pulse of duration equal to the pulse width via a conductor . Pulses with the selected characteristics are then delivered from signal generator 14 through cable 22 and lead 22A to the target locations of a brain B. Microprocessor 200 executes an algorithm to provide stimulation with closed loop feedback control as shown in U.S. Patent No. 5,792,186 entitled "Method and Apparatus of Treating Neurodegenerative Disorders by Electrical Brain Stimulation," and assigned to Medtronic, Inc., which is incorporated herein by reference in its entirety.

Microprocessor 200 executes an algorithm shown in Figures 14-18 in order to provide stimulation with closed loop feedback control. At the time the stimulation device 14 is implanted, the clinician programs certain key parameters into the memory of the implanted device via telemetry. These parameters may be updated subsequently as needed. Step 400 in Figure 14 indicates the process of first choosing whether the neural activity at the stimulation site is to be blocked or facilitated (step 400(1)) and whether the sensor location is one for which an increase in the neural activity at that location is equivalent to an increase in neural activity at the stimulation target or vice



versa (step 400(2)). Next the clinician must program the range of values for pulse width (step 400(3)), amplitude (step 400(4)) and frequency (step 400(5)) which device 14 may use to optimize the therapy. The clinician may also choose the order in which the parameter changes are made (step 400(6)). Alternatively, the clinician may elect to use default values.

5           The algorithm for selecting parameters is different depending on whether the clinician has chosen to block the neural activity at the stimulation target or facilitate the neural activity. Figure 14 details steps of the algorithm to make parameter changes.

10           The algorithm uses the clinician programmed indication of whether the neurons at the particular location of the stimulating electrode are to be facilitated or blocked in order to reduce the neural activity in the target nucleus to decide which path of the parameter selection algorithm to follow (step 420, Figure 15). If the neuronal activity is to be blocked, device 14 first reads the feedback sensor 130 in step 421. If the sensor values indicate the activity in the target neurons is too high (step 422), the algorithm in this embodiment first increases the frequency of stimulation in step 424 provided this increase does not exceed the preset maximum value set by the physician. Step 423 checks for this condition. If the frequency parameter is not at the maximum, the algorithm returns to step 421 through path 421A to monitor the feed back signal from sensor 130. If the frequency parameter is at the maximum, the algorithm next increases the pulse width in step 426 (Figure 16), again with the restriction that this parameter has not exceeded the maximum value as checked for in step 425 through path 423A. Not having reached maximum pulse width, the algorithm returns to step 421 to monitor the feedback signal from sensor 130. Should the maximum pulse width have been reached, the algorithm next increases amplitude in a like manner as shown in steps 427 and

428. In the event that all parameters reach the maximum, a notification message is set in step 429 to be sent by telemetry to the clinician indicating that device 14 is unable to reduce neural activity to the desired level.

If, on the other hand, the stimulation electrode is placed in a location which the clinician would like to activate in order to increase an inhibition of the target nucleus, the algorithm would follow a different sequence of events. In the preferred embodiment, the frequency parameter would be fixed at a value chosen by the clinician to facilitate neuronal activity in step 430 (Figure 17) through path 420A. In steps 431 and 432 the algorithm uses the values of the feedback sensor to determine if neuronal activity is being adequately controlled. In this case, inadequate control indicates that the neuronal activity of the stimulation target is too low. Neuronal activity is increased by first increasing stimulation amplitude (step 434) provided it doesn't exceed the programmed maximum value checked for in step 433. When maximum amplitude is reached, the algorithm increases pulse width to its maximum value in steps 435 and 436 (Figure 18). A lack of adequate reduction of neuronal activity in the target nucleus, even though maximum parameters are used, is indicated to the clinician in step 437. After steps 434, 436 and 437, the algorithm returns to step 431 through path 431A, and the feedback sensor again is read.

It is desirable to reduce parameter values to the minimum level needed to establish the appropriate level of neuronal activity in the target nucleus. Superimposed on the algorithm just described is an additional algorithm to readjust all the parameter levels downward as far as possible. In Figure 14, steps 410 through 415 constitute the method to do this. When parameters are changed, a timer is reset in step 415. If there is no need to change any stimulus parameters before the timer

has counted out, then it may be possible due to changes in neuronal activity to reduce the parameter values and still maintain appropriate levels of neuronal activity in the target neurons. At the end of the programmed time interval, device 14 tries reducing a parameter in step 413 to determine if control is maintained. If it is, the various parameter values will be ratcheted down until such time as the sensor values again indicate a need to increase them. While the algorithms in Figure 14 follow the order of parameter selection indicated, other sequences may be programmed by the clinician.

The features and advantages of the present invention for steering an electric field within a brain, a spinal cord, or a peripheral nerve may be implemented in numerous applications. It is generally desirable to excite particular neural tissue elements of the brain to provide a certain treatment such as treatment of a neurological disorder, the relief of chronic pain or to control movements. Often, nearby groups of neurons or axons, e.g., the optic nerve, internal capsule, or medial lemniscus, are in special orientations and groupings. It may be advantageous to avoid affecting them (e.g., preventing stimulation of the perception of the flashes of light) or deliberately to affect them (e.g., excite or inhibit axons of passage). Advantageously, the present invention allows steering of the electrical field in two- or three-dimensional space such that the precise location and orientation of the electrodes is less critical.

Closed-loop feedback control may also be implemented to steer the electric field to more precisely affect the desired treatment volume of neural tissue.

Referring back to Figure 11, the present invention may also be implemented within a drug delivery system. In this embodiment, the therapy delivery device is a pump 10A and the therapy delivery element is a catheter 23. A therapy delivery device or pump 10A made in accordance with

the preferred embodiment may be implanted below the skin of a patient. The device has a port 27 into which a hypodermic needle can be inserted through the skin to inject a quantity of a liquid agent, such as a medication or drug. The liquid agent is delivered from pump 10A through a catheter port 20A into a therapy delivery element or a catheter 23. Catheter 23 is positioned to deliver the agent to specific infusion sites in a brain (B). Pump 10A may take the form of the device numbered 10 that is shown in U.S. Patent No. 4,692,147 (Duggan), assigned to Medtronic, Inc., Minneapolis, Minnesota, which is incorporated by reference in its entirety.

The distal end of catheter 23 terminates in a cylindrical hollow tube 23A having a distal end implanted into a portion of the brain B by conventional stereotactic surgical techniques. Tube 23A is surgically implanted through a hole in the skull 123. Catheter 23 is joined to pump 10A in the manner shown.

The present invention may be used to deliver treatment therapy to any number of sites in the brain. Particular sites within the brain include, for example, the subthalamic nucleus (STN), the peduncular pontine nucleus (PPN), the caudate or putamen, the internal and external pallidum, the cingulum, the anterior limb of the internal capsule, the anterior nucleus (AN), the centromedian (CM), the dorsal medial nucleus and other nuclei of the thalamus, the hippocampus and other structures in the temporal lobe, the hypothalamus and other structures of the diencephalon, the pons, the medulla, the cortex, the cerebellum, the lateral geniculate body, and the medial geniculate body. The desired configuration of the electrodes would depend upon the structure of the portion of the brain to be stimulated or infused and the angle of introduction of the deep brain cannula.

Further, lamina for visual fields are found in the lateral geniculate body, and lamina for tones for hearing are found in the medial geniculate body. Hence, steering of excitation or inhibition by use of this invention can be most useful.

Leads of the present invention may also be placed into the parenchyma of the spinal cord.

For example, an electrode array may be located in the region of a specified spinal cord segment where neural tissue related to the bladder may be influenced. Selective activation of regions of the ventral horn of the spinal cord in these spinal segments may enable selective activation of specific actions related to bladder function. Alternatively, placement of leads in the region of the conus medullaris (Figure 22) or cauda equina (Figure 21) may further enhance the ability to selectively activate element of urinary bladder control. Leads 975 or 980 of Figures 21 or 22 may be implanted under known techniques for implanting leads within the spinal cord.

As shown in Figure 23, leads of the present invention may also be placed in a peripheral nerve to provide selective activation of individual nerve fascicles or neurons each innervating a different body region or subserving a different physiological function. Selective activation individual nerve fascicles or neurons may allow discrimination of regions of body surface when evoking paresthesia activation to treat chronic pain. Alternatively, such an embodiment would allow selective activation of different muscle groups when performing functional electrical stimulation.

Advantageously, the present invention may be used to selectively steer and control the stimulation of neurons or neural tissue to deliver a desired treatment therapy. Those skilled in that art will recognize that the preferred embodiments may be altered or amended without departing from the true spirit and scope of the invention, as defined in the accompanying claims. For example, the

present invention may also be implemented within a drug delivery system where the leads are implanted within the brain in accordance with the present invention to provide electrical stimulation as well as delivery of one or more drugs.

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65  
66  
67  
68  
69  
70  
71  
72  
73  
74  
75  
76  
77  
78  
79  
80  
81  
82  
83  
84  
85  
86  
87  
88  
89  
90  
91  
92  
93  
94  
95  
96  
97  
98  
99  
100  
101  
102  
103  
104  
105  
106  
107  
108  
109  
110  
111  
112  
113  
114  
115  
116  
117  
118  
119  
120  
121  
122  
123  
124  
125  
126  
127  
128  
129  
130  
131  
132  
133  
134  
135  
136  
137  
138  
139  
140  
141  
142  
143  
144  
145  
146  
147  
148  
149  
150  
151  
152  
153  
154  
155  
156  
157  
158  
159  
160  
161  
162  
163  
164  
165  
166  
167  
168  
169  
170  
171  
172  
173  
174  
175  
176  
177  
178  
179  
180  
181  
182  
183  
184  
185  
186  
187  
188  
189  
190  
191  
192  
193  
194  
195  
196  
197  
198  
199  
200  
201  
202  
203  
204  
205  
206  
207  
208  
209  
210  
211  
212  
213  
214  
215  
216  
217  
218  
219  
220  
221  
222  
223  
224  
225  
226  
227  
228  
229  
230  
231  
232  
233  
234  
235  
236  
237  
238  
239  
240  
241  
242  
243  
244  
245  
246  
247  
248  
249  
250  
251  
252  
253  
254  
255  
256  
257  
258  
259  
260  
261  
262  
263  
264  
265  
266  
267  
268  
269  
270  
271  
272  
273  
274  
275  
276  
277  
278  
279  
280  
281  
282  
283  
284  
285  
286  
287  
288  
289  
290  
291  
292  
293  
294  
295  
296  
297  
298  
299  
300  
301  
302  
303  
304  
305  
306  
307  
308  
309  
310  
311  
312  
313  
314  
315  
316  
317  
318  
319  
320  
321  
322  
323  
324  
325  
326  
327  
328  
329  
330  
331  
332  
333  
334  
335  
336  
337  
338  
339  
340  
341  
342  
343  
344  
345  
346  
347  
348  
349  
350  
351  
352  
353  
354  
355  
356  
357  
358  
359  
360  
361  
362  
363  
364  
365  
366  
367  
368  
369  
370  
371  
372  
373  
374  
375  
376  
377  
378  
379  
380  
381  
382  
383  
384  
385  
386  
387  
388  
389  
390  
391  
392  
393  
394  
395  
396  
397  
398  
399  
400  
401  
402  
403  
404  
405  
406  
407  
408  
409  
410  
411  
412  
413  
414  
415  
416  
417  
418  
419  
420  
421  
422  
423  
424  
425  
426  
427  
428  
429  
430  
431  
432  
433  
434  
435  
436  
437  
438  
439  
440  
441  
442  
443  
444  
445  
446  
447  
448  
449  
450  
451  
452  
453  
454  
455  
456  
457  
458  
459  
460  
461  
462  
463  
464  
465  
466  
467  
468  
469  
470  
471  
472  
473  
474  
475  
476  
477  
478  
479  
480  
481  
482  
483  
484  
485  
486  
487  
488  
489  
490  
491  
492  
493  
494  
495  
496  
497  
498  
499  
500  
501  
502  
503  
504  
505  
506  
507  
508  
509  
510  
511  
512  
513  
514  
515  
516  
517  
518  
519  
520  
521  
522  
523  
524  
525  
526  
527  
528  
529  
530  
531  
532  
533  
534  
535  
536  
537  
538  
539  
540  
541  
542  
543  
544  
545  
546  
547  
548  
549  
550  
551  
552  
553  
554  
555  
556  
557  
558  
559  
560  
561  
562  
563  
564  
565  
566  
567  
568  
569  
570  
571  
572  
573  
574  
575  
576  
577  
578  
579  
580  
581  
582  
583  
584  
585  
586  
587  
588  
589  
590  
591  
592  
593  
594  
595  
596  
597  
598  
599  
600  
601  
602  
603  
604  
605  
606  
607  
608  
609  
610  
611  
612  
613  
614  
615  
616  
617  
618  
619  
620  
621  
622  
623  
624  
625  
626  
627  
628  
629  
630  
631  
632  
633  
634  
635  
636  
637  
638  
639  
640  
641  
642  
643  
644  
645  
646  
647  
648  
649  
650  
651  
652  
653  
654  
655  
656  
657  
658  
659  
660  
661  
662  
663  
664  
665  
666  
667  
668  
669  
670  
671  
672  
673  
674  
675  
676  
677  
678  
679  
680  
681  
682  
683  
684  
685  
686  
687  
688  
689  
690  
691  
692  
693  
694  
695  
696  
697  
698  
699  
700  
701  
702  
703  
704  
705  
706  
707  
708  
709  
710  
711  
712  
713  
714  
715  
716  
717  
718  
719  
720  
721  
722  
723  
724  
725  
726  
727  
728  
729  
730  
731  
732  
733  
734  
735  
736  
737  
738  
739  
740  
741  
742  
743  
744  
745  
746  
747  
748  
749  
750  
751  
752  
753  
754  
755  
756  
757  
758  
759  
760  
761  
762  
763  
764  
765  
766  
767  
768  
769  
770  
771  
772  
773  
774  
775  
776  
777  
778  
779  
780  
781  
782  
783  
784  
785  
786  
787  
788  
789  
790  
791  
792  
793  
794  
795  
796  
797  
798  
799  
800  
801  
802  
803  
804  
805  
806  
807  
808  
809  
810  
811  
812  
813  
814  
815  
816  
817  
818  
819  
820  
821  
822  
823  
824  
825  
826  
827  
828  
829  
830  
831  
832  
833  
834  
835  
836  
837  
838  
839  
840  
841  
842  
843  
844  
845  
846  
847  
848  
849  
850  
851  
852  
853  
854  
855  
856  
857  
858  
859  
860  
861  
862  
863  
864  
865  
866  
867  
868  
869  
870  
871  
872  
873  
874  
875  
876  
877  
878  
879  
880  
881  
882  
883  
884  
885  
886  
887  
888  
889  
890  
891  
892  
893  
894  
895  
896  
897  
898  
899  
900  
901  
902  
903  
904  
905  
906  
907  
908  
909  
910  
911  
912  
913  
914  
915  
916  
917  
918  
919  
920  
921  
922  
923  
924  
925  
926  
927  
928  
929  
930  
931  
932  
933  
934  
935  
936  
937  
938  
939  
940  
941  
942  
943  
944  
945  
946  
947  
948  
949  
950  
951  
952  
953  
954  
955  
956  
957  
958  
959  
960  
961  
962  
963  
964  
965  
966  
967  
968  
969  
970  
971  
972  
973  
974  
975  
976  
977  
978  
979  
980  
981  
982  
983  
984  
985  
986  
987  
988  
989  
990  
991  
992  
993  
994  
995  
996  
997  
998  
999  
1000  
1001  
1002  
1003  
1004  
1005  
1006  
1007  
1008  
1009  
1010  
1011  
1012  
1013  
1014  
1015  
1016  
1017  
1018  
1019  
1020  
1021  
1022  
1023  
1024  
1025  
1026  
1027  
1028  
1029  
1030  
1031  
1032  
1033  
1034  
1035  
1036  
1037  
1038  
1039  
1040  
1041  
1042  
1043  
1044  
1045  
1046  
1047  
1048  
1049  
1050  
1051  
1052  
1053  
1054  
1055  
1056  
1057  
1058  
1059  
1060  
1061  
1062  
1063  
1064  
1065  
1066  
1067  
1068  
1069  
1070  
1071  
1072  
1073  
1074  
1075  
1076  
1077  
1078  
1079  
1080  
1081  
1082  
1083  
1084  
1085  
1086  
1087  
1088  
1089  
1090  
1091  
1092  
1093  
1094  
1095  
1096  
1097  
1098  
1099  
1100  
1101  
1102  
1103  
1104  
1105  
1106  
1107  
1108  
1109  
1110  
1111  
1112  
1113  
1114  
1115  
1116  
1117  
1118  
1119  
1120  
1121  
1122  
1123  
1124  
1125  
1126  
1127  
1128  
1129  
1130  
1131  
1132  
1133  
1134  
1135  
1136  
1137  
1138  
1139  
1140  
1141  
1142  
1143  
1144  
1145  
1146  
1147  
1148  
1149  
1150  
1151  
1152  
1153  
1154  
1155  
1156  
1157  
1158  
1159  
1160  
1161  
1162  
1163  
1164  
1165  
1166  
1167  
1168  
1169  
1170  
1171  
1172  
1173  
1174  
1175  
1176  
1177  
1178  
1179  
1180  
1181  
1182  
1183  
1184  
1185  
1186  
1187  
1188  
1189  
1190  
1191  
1192  
1193  
1194  
1195  
1196  
1197  
1198  
1199  
1200  
1201  
1202  
1203  
1204  
1205  
1206  
1207  
1208  
1209  
1210  
1211  
1212  
1213  
1214  
1215  
1216  
1217  
1218  
1219  
1220  
1221  
1222  
1223  
1224  
1225  
1226  
1227  
1228  
1229  
1230  
1231  
1232  
1233  
1234  
1235  
1236  
1237  
1238  
1239  
1240  
1241  
1242  
1243  
1244  
1245  
1246  
1247  
1248  
1249  
1250  
1251  
1252  
1253  
1254  
1255  
1256  
1257  
1258  
1259  
1260  
1261  
1262  
1263  
1264  
1265  
1266  
1267  
1268  
1269  
1270  
1271  
1272  
1273  
1274  
1275  
1276  
1277  
1278  
1279  
1280  
1281  
1282  
1283  
1284  
1285  
1286  
1287  
1288  
1289  
1290  
1291  
1292  
1293  
1294  
1295  
1296  
1297  
1298  
1299  
1300  
1301  
1302  
1303  
1304  
1305  
1306  
1307  
1308  
1309  
1310  
1311  
1312  
1313  
1314  
1315  
1316  
1317  
1318  
1319  
1320  
1321  
1322  
1323  
1324  
1325  
1326  
1327  
1328  
1329  
1330  
1331  
1332  
1333  
1334  
1335  
1336  
1337  
1338  
1339  
1340  
1341  
1342  
1343  
1344  
1345  
1346  
1347  
1348  
1349  
1350  
1351  
1352  
1353  
1354  
1355  
1356  
1357  
1358  
1359  
1360  
1361  
1362  
1363  
1364  
1365  
1366  
1367  
1368  
1369  
1370  
1371  
1372  
1373  
1374  
1375  
1376  
1377  
1378  
1379  
1380  
1381  
1382  
1383  
1384  
1385  
1386  
1387  
1388  
1389  
1390  
1391  
1392  
1393  
1394  
1395  
1396  
1397  
1398  
1399  
1400  
1401  
1402  
1403  
1404  
1405  
1406  
1407  
1408  
1409  
1410  
1411  
1412  
1413  
1414  
1415  
1416  
1417  
1418  
1419  
1420  
1421  
1422  
1423  
1424  
1425  
1426  
1427  
1428  
1429  
1430  
1431  
1432  
1433  
1434  
1435  
1436  
1437  
1438  
1439  
1440  
1441  
1442  
1443  
1444  
1445  
1446  
1447  
1448  
1449  
1450  
1451  
1452  
1453  
1454  
1455  
1456  
1457  
1458  
1459  
1460  
1461  
1462  
1463  
1464  
1465  
1466  
1467  
1468  
1469  
1470  
1471  
1472  
1473  
1474  
1475  
1476  
1477  
1478  
1479  
1480  
1481  
1482  
1483  
1484  
1485  
1486  
1487  
1488  
1489  
1490  
1491  
1492  
1493  
1494  
1495  
1496  
1497  
1498  
1499  
1500  
1501  
1502  
1503  
1504  
1505  
1506  
1507  
1508  
1509  
1510  
1511  
1512  
1513  
1514  
1515  
1516  
1517  
1518  
1519  
1520  
1521  
1522  
1523  
1524  
1525  
1526  
1527  
1528  
1529  
1530  
1531  
1532  
1533  
1534  
1535  
1536  
1537  
1538  
1539  
1540  
1541  
1542  
1543  
1544  
1545  
1546  
1547  
1548  
1549  
1550  
1551  
1552  
1553  
1554  
1555  
1556  
1557  
1558  
1559  
1560  
1561  
1562  
1563  
1564  
1565  
1566  
1567  
1568  
1569  
1570  
1571  
1572  
1573  
1574  
1575  
1576  
1577  
1578  
1579  
1580  
1581  
1582  
1583  
1584  
1585  
1586  
1587  
1588  
1589  
1590  
1591  
1592  
1593  
1594  
1595  
1596  
1597  
1598  
1599  
1600  
1601  
1602  
1603  
1604  
1605  
1606  
1607  
1608  
1609  
1610  
1611  
1612  
1613  
1614  
1615  
1616  
1617  
1618  
1619  
1620  
1621  
1622  
1623  
1624  
1625  
1626  
1627  
1628  
1629  
1630  
1631  
1632  
1633  
1634  
1635  
1636  
1637  
1638  
1639  
1640  
1641  
1642  
1643  
1644  
1645  
1646  
1647  
1648  
1649  
1650  
1651  
1652  
1653  
1654  
1655  
1656  
1657  
1658  
1659  
1660  
1661  
1662  
1663  
1664  
1665  
1666  
1667  
1668  
1669  
1670  
1671  
1672  
1673  
1674  
1675  
1676  
1677  
1678  
1679  
1680  
1681  
1682  
1683  
1684  
1685  
1686  
1687  
1688  
1689  
1690  
1691  
1692  
1693  
1694  
1695  
1696  
1697  
1698  
1699  
1700  
1701  
1702  
1703  
1704  
1705  
1706  
1707  
1708  
1709  
1710  
1711  
1712  
1713  
1714  
1715  
1716  
1717  
1718  
1719  
1720  
1721  
1722  
1723  
1724  
1725  
1726  
1727  
1728  
1729  
1730  
1731  
1732  
1733  
1734  
1735  
1736  
1737  
1738  
1739  
1740  
1741  
1742  
1743  
1744  
1745  
1746  
1747  
1748  
1749  
1750  
1751  
1752  
1753  
1754  
1755  
1756  
1757  
1758  
1759  
1760  
1761  
1762  
1763  
1764  
1765  
1766  
1767  
1768  
1769  
1770  
1771  
1772  
1773  
1774  
1775  
1776  
1777  
1778  
1779  
1780  
1781  
1782  
1783  
1784  
1785  
1786  
1787  
1788  
1789  
1790  
1791  
1792  
1793  
1794  
1795  
1796  
1797  
1798  
1799  
1800  
1801  
1802  
1803  
1804  
1805  
1806  
1807  
1808  
1809  
1810  
1811  
1812  
1813  
1814  
1815  
1816  
1817  
1818  
1819  
1820  
1821  
1822  
1823  
1824  
1825  
1826  
1827  
1828  
1829  
1830  
1831  
1832  
1833  
1834  
1835  
1836  
1837  
1838  
1839  
1840  
1841  
1842  
1843  
1844  
1845  
1846  
1847  
1848  
1849  
1850  
1851  
1852  
1853  
1854  
1855  
1856  
1857  
1858  
1859  
1860  
1861  
1862  
1863  
1864  
1865  
1866  
1867  
1868  
1869  
1870  
1871  
1872  
1873  
1874  
1875  
1876  
1877  
1878  
1879  
1880  
1881  
1882  
1883  
1884  
1885  
1886  
1887  
1888  
1889  
1890  
1891  
1892  
1893  
1894  
1895  
1896  
1897  
1898  
1899  
1900  
1901  
1902  
1903  
1904  
1905  
1906  
1907  
1908  
1909  
1910  
1911  
1912  
1913  
1914  
1915  
1916  
1917  
1918  
1919  
1920  
1921  
1922  
1923  
1924  
1925  
1926  
1927  
1928  
1929  
1930  
1931  
1932  
1933  
1934  
1935  
1936  
1937  
1938  
1939  
1940  
1941  
1942  
1943  
1944  
1945  
1946  
1947  
1948  
1949  
1950  
1951  
1952  
1953  
1954  
1955  
1956  
1957  
1958  
1959  
1960  
1961  
1962  
1963  
1964  
1965  
1966  
1967  
1968  
1969  
1970  
1971  
1972  
1973  
1974  
1975  
1976  
1977  
1978  
1979  
1980  
1981  
1982  
1983  
1984  
1985  
1986  
1987  
1988  
1989  
1990  
1991  
1992  
1993  
1994  
1995  
1996  
1997  
1998  
1999  
2000  
2001  
2002  
2003  
2004  
2005  
2006  
2007  
2008  
2009  
2010  
2011  
2012  
2013  
2014  
2015  
2016  
2017  
2018  
2019  
2020  
2021  
2022  
2023  
2024  
2025  
2026  
2027  
2028  
2029  
2030  
2031  
2032  
2033  
2034  
2035  
2036  
2037  
2038  
2039  
2040  
2041  
2042  
2043  
2044  
2045  
2046  
2047  
2048  
2049  
2050  
2051  
2052  
2053  
2054  
2055  
2056  
2057  
2058  
2059  
2060  
2061  
2062  
2063  
2064  
2065  
2066  
2067  
2068  
2069  
2070  
2071  
2072  
2073  
2074  
2075  
2076  
2077  
2078  
2079  
2080  
2081  
2082  
2083  
2084  
2085  
2086  
2087  
2088  
2089  
2090  
2091  
2092  
2093  
2094  
2095  
2096  
2097  
2098  
2099  
2100  
2101  
2102  
2103  
2104  
2105  
2106  
2107  
2108  
2109  
2110  
2111  
2112  
2113  
2114  
2115  
2116  
2117  
2118  
2119  
2120  
2121  
2122  
2123  
2124  
2125  
2126  
2127  
2128  
2129  
2130  
2131  
2132  
2133  
2134  
2135  
2136  
2137  
2138  
2139  
2140  
2141  
2142  
2143  
2144  
2145  
2146  
2147  
2148  
2149  
2150  
2151  
2152  
2153  
2154  
2155  
2156  
2157  
2158  
2159  
2160  
2161  
2162  
2163  
2164  
2165  
2166  
2167  
2168  
2169  
2170  
2171  
2172  
2173  
2174  
2175  
2176  
2177  
2178  
2179  
2180  
2181  
2182  
2183  
2184  
2185  
2186  
2187  
2188  
2189  
2190  
2191  
2192  
2193  
2194  
2195  
2196  
2197  
2198  
2199  
2200  
2201  
2202  
2203  
2204  
2205  
2206  
2207  
2208  
2209  
2210  
2211  
2212  
2213  
2214  
2215  
2216  
2217  
2218  
2219  
2220  
2221  
2222  
2223  
2224  
2225  
2226  
2227  
2228  
2229  
2230  
2231  
2232  
2233